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10/581,964	06/07/2006	Antonio Ricci	72270	7292

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MCGLEW & TUTTLE, PC
P.O. BOX 9227
SCARBOROUGH STATION
SCARBOROUGH, NY 10510-9227

EXAMINER	
SAKELARIS, SALLY A	
ART UNIT	PAPER NUMBER
1797	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,964	RICCI ET AL.	
	Examiner	Art Unit	
	SALLY A. SAKELARIS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/29/2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-34 and 41-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-34 and 41-52* is/are rejected.

7)☒ Claim(s) *1-11,13-34 and 41-47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendment filed 10/29/2009 has been received and considered for examination. Claims 1-11, 13-34, 41-45 and new claims 46-52 remain pending. Claims 12 and 35-40 have been cancelled.

Claim Objections

Claims 1-11, 13-34, and 41-47 are objected to because of the following informalities: Claim 1 recites "erytrocyte" in its first line. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-11, 13-17, 21-28, 41-44, and 46-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Skotnikov et al. (US 5526705).

Applicant should note that the recitation in the preamble for measuring sedimentation rate in biological samples and in especially blood samples has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The prior art has been applied appropriately.

With regard to claims 1, 44, 48, and 51, Skotnikov et al. in Figure 1 teach holders (i.e., links in the belt (36) Col. 10 line 20-22) for test tubes (vessels (32) containing samples of biological fluids; agitator devices (40, 50, 100) for agitating said test tubes (32); at least one detector (78, 180 as an example) for detecting the levels inside said test tubes; characterized in that wherein said holders (links in the belt sized to snugly fit about an outer perimeter of vessels 32) are formed in a continuous flexible member (Figure 3) defining a closed path, along which said agitator devices (Figure 1 40, 50 and 100) and said at least one detector (78, Fig.1) are arranged.

With regard to claim 1's new limitations, Skotnikov teach FIG. 1 that is a schematic representation of automated work station 10 according to the present invention. Automated work station 10 includes sample preparation station (or line) 12 and a plurality of test stations, or testing lines A, B, C, D, F, G, H and J each with various detectors (i.e., at least one and two detectors). Test station A determines soil acidity, test station B determines soil carbon content, test station C is used to prepare a soil extract which is eventually provided to ion-selective flow sensors for the determination of nutrients and micronutrients in the sample, test station F determines alkali soluble fraction of organic matters, test station G is used to determine organic matter, test station H is used to determine sesquioxides, and test station J is used to determine dust, sand and physical clay in the sample. Various detectors (i.e., sensors) in the testing lines are coupled to controller interface 14 which is, in turn, coupled to controller 16.

With regard to claim 2, Skotnikov et al. teaches agitators (40, 50, and 100) (Col. 4 lines 16-22). 100 is taught to be a dedicated stirrer (Col. 6 line 50).

With regard to claims 3 and 41, Skotnikov et al. teach the following are arranged along the closed path of the device: one agitating area (Fig. 1, 45, 50, 100) at least one sedimentation area (following each of 45, 50, and 100 in Fig. 1); And at least one reading area wherein said detector is installed (78 in Fig. 1).

With regard to claims 4, 42, and 43, the flexible member (36) lies along a horizontal plane.

With regard to claims 5-9, 46, 47, 49, 50, and 52 Skotnikov teach that the holders fit within a flexible member (i.e., each of the testing lines A-J in Figure 1) and the holders represent the links that fit each outside perimeter of each vessel (Col. 10) and further that within these links oscillation (i.e. agitation) is possible at various locations (stations) within the device (e.g. 40, 50, 100) outside the plane on which the flexible member lies.

With regard to claim 10-15, Skotnikov teach agitators (i.e. 40, 50, 100 and sprockets (140) Fig. 3) that act as guides. The intersection with the conveyor holders can be viewed as "sliding shoes" and are slidingly engaged in the absence of a figure showing that which applicant intends to be claiming with this recitation. Skotnikov also teach agitating fixed guides in the form of sprockets 140 (rotor coaxial in Fig. 3) and mobile guides that are arranged to induce agitation in the form of 40, 50, and 100. The sprockets are shown in Fig 3 to be provided with elements for engaging the holders and capable of rotating around its own axis.

With regard to claims 16 and 17, Skotnikov teach FIG. 1 that is a schematic representation of automated work station 10 according to the present invention. Automated work station 10 includes sample preparation station (or line) 12 and a plurality of test stations, or testing lines A, B, C, D, F, G, H and J each with various detectors. Test station A determines

soil acidity, test station B determines soil carbon content, test station C is used to prepare a soil extract which is eventually provided to ion-selective flow sensors for the determination of nutrients and micronutrients in the sample, test station F determines alkali soluble fraction of organic matters, test station G is used to determine organic matter, test station H is used to determine sesquioxides, and test station J is used to determine dust, sand and physical clay in the sample. Various detectors (i.e., sensors) in the testing lines are coupled to controller interface 14 which is, in turn, coupled to controller 16.

With regard to claims 21-28, applicant should note that a recitation of the intended use such as those recited for the automatic manipulator of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

With regard to claim 21, Skotnikov teach a robotic manipulator that removes vessels 32 from their holders in the conveyor 36 and replaces vessels 32 in conveyor 36 (Column 10 lines 48-50).

With regard to claims 22-24, Skotnikov teach that separate robotic manipulators are used in line D and in test line J (Col. 10 line 60-61). Therefore there are 2 extractors taught that are capable of moving tubes into and out of the holder.

With regard to claims 25 and 26, Skotnikov teach a setup unit (i.e., a sample prep line (12)) that is above the continuous flexible member (Fig. 1 (36)).

With regard to claims 27 and 28, Skotnikov teach a controlling unit 16 that receives readings from the reading station, i.e., the humidity meter 28 (Col. 3 lines 45-52).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skotnikov et al. in view of Kaarakainen et al (US 6520313).

The teachings of Skotnikov et al can be seen above.

Skotnikov do not teach a transponder being associated with each holder and test tube, nor do they teach stations for scanning these transponders.

With regard to claims 18-20, Kaarakainen et al. teach transport bases or holders for test tubes (Fig. 1) that incorporate an RF memory circuit, in which data can be entered and read without contact in, for example, a control station, which can then decide which processing point to transfer the holder with test tube to (Col. 3 lines 1-3). Kaarakainen et al goes on to teach that the RF memory circuit, i.e., transponder can be read rapidly and as the small read/write sensor can be located almost anywhere, its location does not restrict the mechanical design of the system (Col. 3 lines 35-38).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to have incorporated the RF transponders and scanners of Kaarakainen et al into the device of Skotnikov et al. as Kaarakainen et al. provide the motivation that the transponders can be read rapidly and that the scanners can be located anywhere in the device which would allow for more efficient processing of samples and would avoid errors due to misidentification of the tubes within their holders.

3. Claims 29-30, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skotnikov et al. in view of Coulter et al. (US 4609017).

The teachings of Skotnikov et al can be seen above.

Skotnikov do not teach a setup unit that comprises a first and second transfer unit with a first and second conveyor for moving a plurality of racks containing test tubes, and a reading unit associated with one of the two.

With regard to claims 29-30 and 32-34, Coulter teach in Figure 2 a setup unit that can be retrofit to an analyzer consisting of a plurality of racks (12) which are stacked vertically above a first conveyor (i.e., input elevator (20)) Col. 4 lines 23-64. The racks are stripped one at a time from the bottom of the stack within the first transfer unit (16) and lowered by the first conveyor (i.e., elevator (20)) onto the second conveyor belt (32) and tilt table en route to the second transfer unit (40). Also, a reading unit is taught within this setup unit there at a time and place during, or just prior to sample aspiration, the identification of the sample is read (50) automatically for correlation with that sample's parameter measurements Col 8, lines 50-68).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to have incorporated the features of Coulter's setup unit into the setup unit of Skotnikov et al. as Coulter teaches his sample setup unit (i.e., sample carrier transport system) is capable of being housed in a stand-alone module, with the aspirated sample then being fed from this module into the main body of the analyzer and furthermore that such module configuration would be useful for retrofit with other styles of analyzers, such as one of Skotnikov et al. for

example. Furthermore, the benefit exists that in Coulter's setup unit many samples may be handled in parallel without a manual step creating a more efficient, high throughput device.

4. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Skotnikov et al. in view of Coulter et al. (US 4609017) and in further view of Roginski (US 4927545).

The teachings of Skotnikov can be viewed above.

Skotnikov et al. do not teach that their robotic manipulators include a lower push bar coming to bear on the test tubes contained in the racks in order to slide said test tubes partially out of said racks and furthermore a mobile clamp for removing the test tubes from the racks and inserting them into corresponding holders in the continuous flexible member.

Coulter et al. teach in Figure 4 and Figure 2 manipulators that include a lower push bar (42) coming to bear on the test tubes contained in the racks in order to slide said test tubes partially out of said racks (Col. 6 lines 49-53).

Coulter et al do not teach a mobile clamp for then removing the test tube from the rack and inserting them into a holder of the continuous flexible member.

Roginski teach in Figure 1 and in claim 12 that a robotic arm adapted to move the test tubes in a variety of ways one by one from a first location to a second. For example the robotic arm (10) with mobile clamp (14) is adapted to remove the test tubes, one at a time, from said input station and move them to the centrifuge, remove the centrifuged test tubes and place them in the optical inspection station, and remove the optically inspected test tubes and place them into either said first or second output station under control of the means for evaluating the electrical signals to determine the success of the separation operation.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to have incorporated the features of Coulter's tube pusher and Roginski's robotic arm into the "robotic manipulator" (Col. 10) of Skotnikov et al. and subsequently into Skotnikov's conveyor device as both the tube pusher of Coulter and Robotic clamp arm of Roginski allow for specialized treatment of each test tube sample adding specificity to a high throughput system achieving therein a flexible and scalable device capable of operating on both micro and macro levels.

Response to Arguments

Applicant's arguments filed 10/29/2009 have been fully considered but they are not persuasive.

Applicant first provides arguments regarding the Skotnikov et al. reference:

However, Skotnikov et al. does not provide any teaching or suggestion for any of the testing stations measuring a level of fluid in a test tube that is held by a holder as claimed. The Office Action takes the position that reference numeral 78 of Skotnikov et al. is the equivalent of the detector of the present invention. Applicant respectfully disagrees as reference numeral 78 of Skotnikov et al. relates to an automated photo-electric calorimeter 78. The calorimeter 78 of Skotnikov et al. only measures the heat created during a reaction and does not measure a level of a fluid in a test tube as claimed. The detection of the level of fluid in the test tubes is a significant feature of the present invention because the erythrocyte sedimentation rate is determined based on the detected levels of the fluid. Skotnikov et al. fails to disclose such erythrocyte sedimentation rate determining features. In fact, Skotnikov et al. does not teach or suggest any measuring arrangement based on detection of levels measured at two positions spaced apart from one another by a sedimentation area as claimed. Skotnikov et al. only discloses that tests are performed at various testing stations, but Skotnikov et al. does not teach or suggest a sedimentation rate that is calculated by comparing data detected at two sequentially arranged spaced apart detection stations as featured in the present invention.

In response, the examiner respectfully disagrees. Skotnikov et al. teaches line J which occupies positions (87-96) of conveyor (36) is used to determine particle size and sedimentation

in the sample and therefore deemed capable of meeting the structural requirements present currently in the claim. Specifically, the calorimeter, (102) is used to measure the sedimentation kinetics of dust, sand, and physical clay particles in the upper third of the vessel (32). These signals are then converted to digital signals via interface (14) and communicated to controller (16) (Col. 6 lines 47-67).

Furthermore, with regard to claims 1, 44, 48, and 51, applicant is considered to be arguing process or intended use limitations in their claims such as: "measured at 2 positions...", "calculated by comparing data detected at...", "erythrocyte determining features", "the holder are rotated", "stirring or mixing" etc. It should be noted that these types of recited, intended uses which do not further delineate the structure of the claimed apparatus from that of the prior art have not been afforded patentable weight. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. These recited process or intended use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See In re Casey, 152 USPQ 235 (CCPA 1967); and In re Otto, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that the

manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See Ex Parte Masham, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

Next applicant addresses the other rejections of record but does not provide any substantive arguments specific to the individual reference save Skotnikov et al. As responded to above, applicant argues that the Skotnikov reference does not teach or suggest that their stations "determine an erythrocyte sedimentation rate". Again, applicant is reminded that this recitation in the preamble without the recitation of structural components that equip the device to specifically be capable of determining this rate, is viewed as being an intended use and further the device of Skotnikov et al. is interpreted as being capable of performing this intended use in various different lines of their device as asserted above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SALLY A. SAKELARIS whose telephone number is (571)272-6297. The examiner can normally be reached on Monday-Friday 8-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 5712721267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SS

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

1/6/2010